

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 08-cv-00317
)	
SANDOZ, INC.)	Jury Trial Demanded
)	
Defendant.)	

**DEFENDANT SANDOZ, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT**

Defendant Sandoz, Inc. ("Sandoz"), for its Answer, Affirmative Defenses, and
Counterclaims to Wyeth's Complaint, states as follows:

The Parties

1. Plaintiff Wyeth is a corporation organized and existing under the laws of Delaware and has its headquarters at 5 Giralda Farms, Madison, New Jersey 07940.

ANSWER:

Sandoz admits on information and belief the allegations in paragraph 1.

2. Upon information and belief, Defendant Sandoz, Inc. is a corporation organized and existing under the laws of Colorado, has its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, and does business in the State of Delaware.

ANSWER:

Sandoz admits the allegations in paragraph 2.

3. Upon information and belief, Sandoz is in the business of manufacturing, distributing and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

ANSWER:

Sandoz admits that it manufactures, distributes, and sells generic pharmaceutical products. Sandoz denies the remaining allegations in paragraph 3.

Jurisdiction and Venue

4. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 6,500,814 (“the ‘814 patent”). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

Sandoz admits that Wyeth’s Complaint purports to be an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. Sandoz further admits that Wyeth has asserted United States Patent No. 6,500,814 (“the ‘814 patent”) against Sandoz in this action. Sandoz further admits that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Sandoz denies the remaining allegations in paragraph 4.

5. This Court has personal jurisdiction over Sandoz based on Sandoz’s continuous and systematic business contacts with the State of Delaware. Additionally, in a telephone conversation on May 23, 2008, counsel for Sandoz agreed that Sandoz would not contest jurisdiction in this judicial district for this action.

ANSWER:

Sandoz admits that it advised Wyeth that it would not contest personal jurisdiction in this Court for purposes of this action. Sandoz accordingly does not contest personal jurisdiction in this judicial district for purposes of this action. Sandoz denies the remaining allegations in paragraph 5.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER:

Sandoz admits that venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Count 1: Patent Infringement

7. Wyeth realleges paragraphs 1 through 6 above as if fully set forth herein.

ANSWER:

Sandoz repeats and reasserts its answers to the allegations set forth in paragraphs 1 through 6 above as though fully set forth herein.

8. On December 31, 2002, the United States Patent and Trademark Office duly and legally issued the '814 patent, entitled "Hormonal Contraceptive." A true and correct copy of the '814 patent is attached hereto as Exhibit A.

ANSWER:

Sandoz admits that what purports to be a copy of the '814 patent is attached to Wyeth's Complaint as Exhibit A. Sandoz further admits that Exhibit A lists an issue date of December 31, 2002. Sandoz denies that the '814 patent was duly and legally issued by the United States Patent and Trademark Office. Sandoz is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 8, and therefore denies the same.

9. Wyeth is the assignee of the '814 patent, which discloses and claims, *inter alia*, methods for hormonal contraception.

ANSWER:

Sandoz admits only that the claims of the '814 patent speak for themselves. Sandoz denies the allegations in paragraph 9 to the extent they are inconsistent with the claims of the '814 patent. Sandoz is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 9, and therefore denies the same.

10. Wyeth currently markets a prescription oral contraceptive product under the trademark LYBREL[®] pursuant to approved New Drug Application ("NDA") 21-864. LYBREL[®] is covered by the claims of the '814 patent. As the patent owner, Wyeth is authorized to enforce the '814 patent.

ANSWER:

Sandoz admits upon information and belief that Wyeth markets a prescription oral contraceptive product under the trade name of LYBREL® in the United States pursuant to approved NDA 21-864. Sandoz denies that the '814 patent is valid and/or enforceable. Sandoz is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 10, and therefore denies the same.

11. Upon information and belief, Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 90-262 ("Sandoz ANDA") to the Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale and sale of a generic version of LYBREL® before the expiration of the '814 patent.

ANSWER:

Sandoz admits that it submitted Abbreviated New Drug Application ("ANDA") No. 90-262 to the Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale and sale of Sandoz's proposed ethinyl estradiol; levonorgestrel oral tablets, 0.02mg; 0.09mg before the expiration of the '814 patent. Sandoz denies the remaining allegations of paragraph 11.

12. On or about April 18, 2008, Plaintiff received a letter dated April 16, 2008 stating that Sandoz had filed the Sandoz ANDA seeking approval to manufacture, use and sell a generic version of LYBREL® before the expiration of the '814 patent. The letter purports to notify Wyeth that the Sandoz ANDA contains a certification pursuant to Title I of the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), that Sandoz's manufacture, use or sale of the Sandoz ANDA product will not infringe any claims of the '814 patent, that the '814 patent is invalid, and/or that the '814 patent is unenforceable.

ANSWER:

Sandoz admits that in a letter dated April 16, 2008, Sandoz notified Wyeth that Sandoz has submitted ANDA No. 90-262 to the FDA seeking approval to engage in the commercial

manufacture, use, offer for sale and sale of Sandoz's proposed ethinyl estradiol; levonorgestrel oral tablets, 0.02mg; 0.09mg before the expiration of the '814 patent. Sandoz further admits that this letter notified Wyeth that Sandoz's ANDA No. 90-262 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that Sandoz's manufacture, use or sale of its ANDA product will not infringe any claims of the '814 patent, that the '814 patent is invalid, and/or that the '814 patent is unenforceable. Sandoz denies the remaining allegations in paragraph 12.

13. Defendant is liable for infringement of the '814 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to expiration of the '814 patent.

ANSWER:

Sandoz denies the allegations in paragraph 13.

14. Wyeth is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Sandoz ANDA be a date that is not a date earlier than the expiration of the '814 patent, or any later expiration of exclusivity for the '814 patent to which Wyeth is or becomes entitled.

ANSWER:

Sandoz denies the allegations in paragraph 14.

15. This case is an exceptional one, and Wyeth is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

ANSWER:

Sandoz denies the allegations in paragraph 15.

16. Wyeth will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing or contributing to infringement of the '814 patent. Wyeth does not have an adequate remedy at law.

ANSWER:

Sandoz denies the allegations in paragraph 16.

Prayer for Relief

WHEREFORE, Wyeth seeks the following relief:

- A. A judgment that Sandoz has infringed the '814 patent under 35 U.S.C. § 271(e)(2)(A);
- B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Sandoz ANDA, No. 90-262, be not earlier than the expiration date of the '814 patent, or any later expiration of exclusivity for the '814 patent to which Wyeth is or becomes entitled;
- C. A permanent injunction restraining and enjoining Sandoz and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the product described in ANDA No. 90-262;
- D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 90-262 would constitute infringement of the '814 patent, or inducing or contributing to such conduct, by Sandoz pursuant to 35 U.S.C. § 271(a), (b) and/or (c);
- E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- F. Costs and expenses in this action; and
- G. Such further and other relief as this Court determines to be just and proper.

ANSWER: Sandoz specifically denies that Wyeth is entitled to the general or specific relief requested against Sandoz, or to any relief whatsoever, and prays for judgment in favor of Sandoz dismissing this action with prejudice, and awarding Sandoz its reasonable attorneys' fees

pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Sandoz Inc. (“Sandoz”) avers and asserts the following Affirmative Defenses to Plaintiff Wyeth’s Complaint.

**FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 6,500,814)**

The manufacture, use, sale, offer to sell or importation into the United States of Sandoz’s proposed ethinyl estradiol; levonorgestrel oral tablets, 0.02mg; 0.09mg (“Sandoz’s proposed ANDA product”) that are the subject of ANDA 90-262 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 6,500,814 (“the ‘814 patent”) either literally or under the doctrine of equivalents.

**SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 6,500,814)**

Upon information and belief, the claims of the ‘814 patent are invalid and/or unenforceable for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112.

COUNTERCLAIMS

Defendant and Counterclaimant Sandoz, Inc. (“Sandoz”) hereby asserts the following counterclaims against Wyeth:

1. Defendant Sandoz, Inc. (“Sandoz”) is a corporation organized and existing under the laws of the State of Colorado, having a place of business at 506 Carnegie Center Suite 400, Princeton, New Jersey 08540.

2. Upon information and belief, Plaintiff Wyeth is a corporation organized and existing under the laws of the State of Delaware, having an established place of business at 5 Giralda Farms, Madison, New Jersey 07940.

3. As a consequence of Wyeth's Complaint against Sandoz, there is now an existing and continuing justiciable controversy between Wyeth and Sandoz regarding the infringement, validity and enforceability of U.S. Patent No. 6,500,814 ("the '814 patent").

4. This court has jurisdiction over the subject matter of these Counterclaims pursuant to section 1331 and 1338(a) of Title 28 of the United States Code, as they involve substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

5. This court may declare the rights and legal relations of the parties pursuant to section 2201 and 2202 of Title 28 of the United States Code, because Sandoz's Counterclaims present an actual controversy within the Court's jurisdiction that the patent asserted by Wyeth against Sandoz is not infringed and/or is invalid.

6. Venue for these Counterclaims is proper within this judicial District.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '814 PATENT

7. The allegations of Paragraphs 1-6 of Sandoz's Counterclaims are incorporated by reference as though fully set forth herein.

8. Sandoz's counterclaim for declaratory relief is brought pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq.* and 35 U.S.C. §§ 101, *et seq.*

9. Sandoz is entitled to a declaratory judgment that the manufacture, use, sale, offer to sell or importation into the United States of Sandoz's proposed ethinyl estradiol; levonorgestrel, 0.02mg; 0.09mg, oral tablets ("Sandoz's proposed ANDA product") that are the subject of ANDA 90-262 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 6,500,814 ("the '814 patent") either literally or under the doctrine of equivalents.

COUNT II
DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '814 PATENT

10. The allegations in Paragraphs 1-10 of Sandoz's Counterclaims are incorporated by reference as though fully set forth herein.

11. The claims of the '814 patent are invalid and/or unenforceable for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112.

12. Sandoz is entitled to a declaratory judgment that all claims of the '814 Patent are invalid, unenforceable and void pursuant to 35 U.S.C. §§ 101 *et seq.*

PRAYER FOR RELIEF

WHEREFORE, Sandoz respectfully requests the Court to enter judgment against Plaintiff Wyeth as follows:

A. Declaring that Sandoz's proposed ethinyl estradiol; levonorgestrel, 0.02mg; 0.09mg, oral tablets ("Sandoz's proposed ANDA product") that are the subject of ANDA 90-262 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '814 patent;

B. Declaring that U.S. Patent No. 6,500,814 is invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112;

C. Awarding Sandoz its reasonable costs and attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and

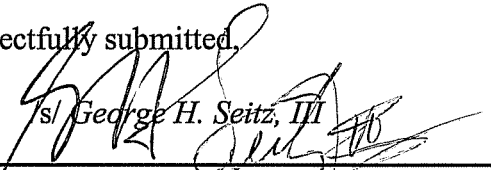
D. Awarding all such other and further relief as this Court may deem just and proper.

JURY DEMAND

Sandoz requests a trial by jury for any issues so triable.

Dated: July 24, 2008

Respectfully submitted,


s/ George H. Seitz, III

George H. Seitz, III (No. 667)
SEITZ, VAN OGTROP & GREEN, P.A.
222 Delaware Avenue, Suite 1500
P.O. Box 68
Wilmington, DE 19899
(302) 888-0600

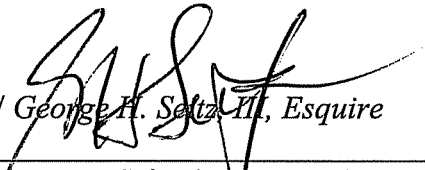
*Attorneys for Defendant
Sandoz Inc.*

Of Counsel:

Keith D. Parr
Scott B. Feder
Kevin M. Nelson
James T. Peterka
LOCKE LORD BISSELL & LIDDELL LLP
111 South Wacker Drive
Chicago, IL 60606
Tel: (312) 443-0700
Fax: (312) 443-0336

CERTIFICATE OF SERVICE

I, *George H. Seitz, III*, Esquire, hereby certify that on this 24th day of July 2008, I electronically filed the foregoing *Defendant Sandoz, Inc.'s Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Complaint* with the Clerk of Court using CM/ECF which will send notification of such filing to all counsel of record.


/s/ *George H. Seitz III, Esquire*

George H. Seitz (ID No. 667)
gseitz@svglaw.com